

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

JAN 30 2008

Laura A. Coruzzi, Esq.
Jones Day
222 East 41st St.
New York, NY 10017

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,133,418

Dear Ms. Coruzzi:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 6,133,418 for a period of 528 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till

Legal Advisor

Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc:

Office of Regulatory Policy

HFD-7

5600 Fishers Lane (Rockwall II Rm 1101)

Rockville, MD 20857

Attention: Beverly Friedman.

RE: Fuzeon® (enfuvirtide) FDA Docket No.: 2004E-0019



Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 VA 20013-1450

JAN 30 2008

Anthony M. Insogna Jones Day 222 East 41st Street New York, NY 10017 In Re: Patent Term Extension Application for U.S. Patent No. 5,661,136

RE: CLOLAR® (clofarabine)

FDA Docket No.: 2006E-0031

Dear Mr. Insogna:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,661,136 for a period of 1,237 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till Legal Advisor

Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc:

Office of Regulatory Policy

HFD-7

5600 Fishers Lane (Rockwall II Rm 1101)

Rockville, MD 20857

Attention: Beverly Friedman

## UNITED STATES PATENT AND TRADEMARK OFFICE

## (12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 5,661,136

(45) ISSUED : August 26, 1997

(75) INVENTOR : John A. Montgomery, et al.

(73) PATENT OWNER : Southern Research Institute

(95) PRODUCT : CLOLAR® (clofarabine)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,661,136 based upon the regulatory review of the product CLOLAR® (clofarabine) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 1,237 days

from August 26, 2014, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this <u>17th day</u> of <u>January</u> 2008.

Jon W. Dudas

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

## UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 6,133,418

(45) ISSUED : October 17, 2000

(75) INVENTOR : Dani Paul Bolognesi, et al.

(73) PATENT OWNER : Duke University

(95) PRODUCT : Fuzeon® (enfuvirtide)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 6,133,418 based upon the regulatory review of the product Fuzeon® (enfuvirtide) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 528 days

from June 7, 2013, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

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I have caused the seal of the United States Patent and Trademark Office to be affixed this <u>17th day of January 2008</u>.

Jon W. Dudas

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office